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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,116

09/08/2003

John P. Willis

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,116	Applicant(s) WILLIS ET AL.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/2010 has been entered.

Double Patenting

The terminal disclaimer filed on 3/9/2010 has been accepted. Accordingly, the double patenting rejection has been obviated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

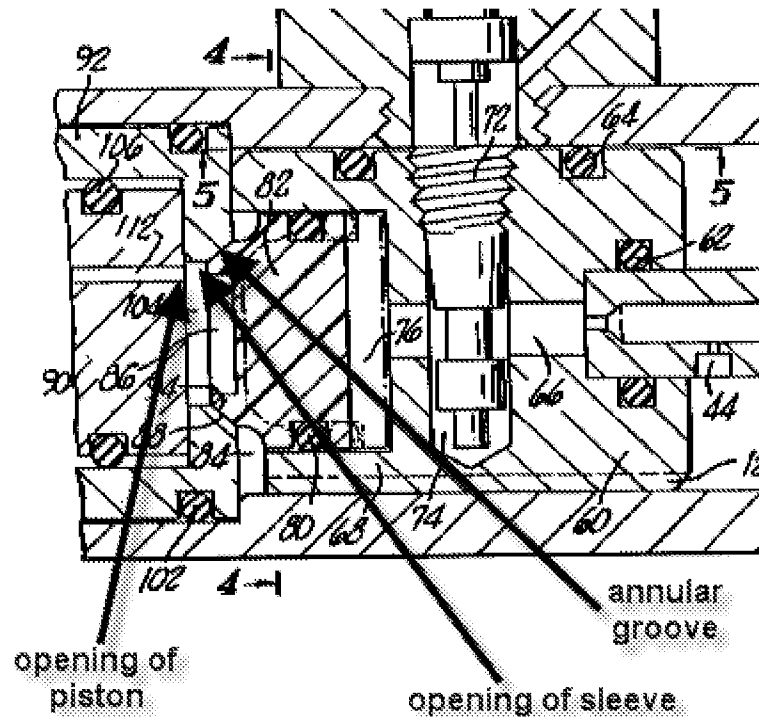
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 36-44, 46, and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by McKinnon et al. (US 5,064,413). McKinnon discloses a device comprising a housing (22) having a proximal end and a distal end, the housing having an opening (the opening of the syringe) proximate the distal end, the opening configured to deliver a fluid, a fluid chamber (syringe chamber) disposed inside the housing and configured to contain the fluid, a propellant chamber (28) disposed inside the housing and spaced from the distal end, a sleeve (92) disposed inside the housing between the distal end and the propellant chamber and having a first cavity (lumen of 92), the first cavity being in fluid communication with the propellant chamber (the lumen of 92 and element 28 are in fluid communication during operation of the device), and a piston (90) coupled with the sleeve and having a second cavity (112) in fluid communication with the first cavity, the piston being movable with respect to the sleeve from a first position to a second position, the piston configured to compress the fluid chamber upon moving from the first position to the second position, wherein the sleeve and piston include at least one opening that are alignable with each other and further wherein the sleeve includes an annular groove with the opening disposed in the groove (see reproduced drawing below), wherein the piston (90) includes at least two openings that are axially spaced from each other, wherein the housing includes a plurality of housing components (the device can be considered to have a plurality of housing components), wherein the propellant chamber includes a propellant (gas), wherein the opening of the piston is not in fluid communication with an exterior of the housing in the first position and being in fluid communication in the second position, wherein the fluid

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chamber includes a plunger (96), wherein the device is a needleless syringe, wherein the piston is coaxial with the sleeve, and further comprising a filter (40).



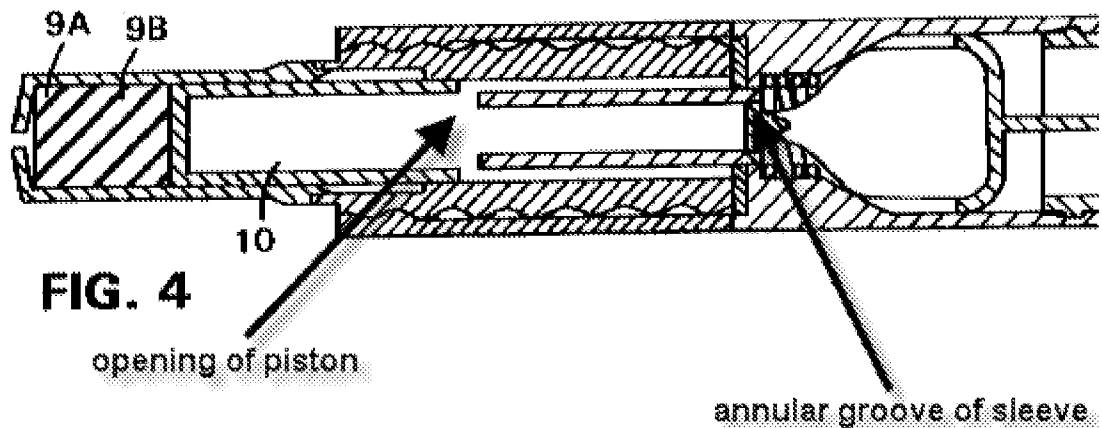
Claims 36-39, 41-44, 46, and 48-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Willis et al. (US 6,406,455).

Willis discloses a device comprising a housing (1,2,3) having a proximal end and a distal end, the housing having an opening (13) proximate the distal end, the opening configured to deliver a fluid, a fluid chamber (13b) disposed inside the housing and configured to contain the fluid, a propellant chamber (6) disposed inside the housing and spaced from the distal end, a sleeve (element defining 11) disposed inside the housing between the distal end and the propellant chamber and having a first cavity (11), the first cavity being in fluid communication with the propellant chamber, and a piston (10) coupled with the sleeve and having a second cavity (lumen of 10) in fluid

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communication with the first cavity, the piston being movable with respect to the sleeve from a first position to a second position, the piston configured to compress the fluid chamber upon moving from the first position to the second position, wherein the sleeve and piston include at least one opening that are alignable with each other and further wherein the sleeve includes an annular groove with the opening disposed in the groove (see reproduced drawing below), wherein the housing includes a plurality of housing components (the device can be considered to have a plurality of housing components), wherein the propellant chamber includes a propellant (gas), wherein the opening of the piston is not in fluid communication with an exterior of the housing in the first position and being in fluid communication in the second position, wherein the fluid chamber includes a plunger (9a, 9b), wherein the device is a needleless syringe, and wherein the piston is coaxial with the sleeve.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon et al. (5,064,413) in view of Haber et al. (5,304,128). McKinnon discloses an injection device that includes all of the limitations recited in the independent claim but fails to teach the gas generant means recited in claims 33 and

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34. Haber discloses an injection device which includes the recited gas generant means. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of McKinnon with the gas generant means of Haber as such a means is known to be an equivalent gas generating means in the art.

Response to Arguments

Applicant's arguments filed 3/9/2010 have been fully considered but they are not persuasive.

The applicant did not provide any arguments. The examiner maintains that the rejection is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763